

Vaccine Briefs

Storage & Handling Toolkit

Our first Vaccine Brief concerns a new tool to help you with vaccine storage and handling. Exposure of vaccines to temperatures outside the recommended ranges can cost your practice thousands of dollars in wasted vaccine and revaccination. Errors in storing and handling your vaccines can also result in the loss of patient confidence in your practice when repeat doses are required.

We hear about vaccine storage and handling disasters far too often. So it is with great pleasure that we announce the availability of a new resource for healthcare personnel who provide immunization services. The Vaccine Storage and Handling Toolkit, which was introduced in March as a web-based resource, will be available within 3 weeks in a CD-ROM format. The Vaccine Storage and Handling Toolkit is a comprehensive resource that provides detailed information on the proper storage and handling of vaccines, including recommendations and resources. The Toolkit covers such topics as maintaining the cold chain, proper equipment and temperature monitoring and vaccine preparation and disposal. The Toolkit includes two popular storage and handling videos: “Top 10 Storage and Handling Errors” and “How to Protect Your Vaccine Supply”. In addition, a fun and interactive training game is included, “The Cold Chain Challenge”. The web-based toolkit is available on the CDC’s National Immunization Program Website. The CD-ROM can be ordered from our online catalog. Bulk copies of the CD will be limited, but a master CD can be ordered for mass duplication. We will include links to both the online version and the ordering system on our broadcast resources and updates web page.

New Vaccines

In this Vaccine Brief we want to tell you about three new vaccines that you may soon be using. License applications have been filed with the Food and Drug Administration for all three vaccines, and they could be approved within the next year. The first of these vaccines of the near future is MMRV. As the name indicates this is a combination of measles, mumps, rubella, and varicella vaccine. It is produced by Merck and will be called PROQUAD™. The application was made in August 2004, so it could be available soon. The application is for children 12 months through 12 years of age. The most important issue for MMRV is that it will require the same storage requirements as varicella vaccine – in the freezer at 5°F at all times. The vaccine cannot be stored in the refrigerator.

The second vaccine of the near future is a new rotavirus vaccine for infants. The vaccine is produced by Merck and is called ROTATEQ™. It is different from the rotavirus vaccine available in the late 1990s in that it is based on a bovine rotavirus reassortant rather than a rhesus monkey virus. The pivotal clinical trial for this vaccine was huge – almost 70,000 children in 11 countries. The vaccine

was found to be effective, and there was no evidence that recipients had an increased risk of intussusception. The application was made in April 2005, so it could be available late this year or early in 2006.

The third vaccine of the near future is intended to reduce the frequency and severity of herpes zoster, or shingles. The vaccine is called ZOSTAVAX™ and is produced by Merck. The vaccine is not just regular Varivax®. It is manufactured with a much higher titer of vaccine virus than regular varicella vaccine. The pivotal clinical trial included more than 36,000 adults 60 to 80 years of age. Compared with the placebo group the vaccine group had about 50% fewer episodes of zoster, and about 66% less post herpetic neuralgia. No significant safety issues were identified in the trial. The vaccine could be available in 2006.

In addition to these three vaccines, FDA has also received applications from 2 manufacturers for new inactivated influenza vaccines. Finally, clinical trials for at least two vaccines for human papilloma virus, or HPV, are nearing completion, and applications for licensure may be made late this year or in early 2006. These vaccines are intended to reduce the risk of cervical cancer caused by HPV. We will bring you more about these new vaccines on future satellite broadcasts.

Vaccine Information Statements

Risk and benefit communication between the provider and the person receiving the vaccine is essential. The cornerstone of immunization patient education is the Vaccine Information Statement, or VIS. Every healthcare provider, public or private, who administers a vaccine covered by the National Childhood Vaccine Injury Act is required by law to provide a copy of the most current VIS with **each dose** of vaccine administered. Not only the first dose, but **every** dose. In addition, CDC encourages healthcare providers to use all available VISs, whether the National Childhood Vaccine Injury Act covers the vaccine or not. It is just good practice.

Healthcare providers should also encourage the patient or their representative to take the VIS home. This is important because the VIS contains information that may be needed later, including the recommended schedule for that vaccine, information concerning what to look for and do after the vaccination, and what to do if there is a serious reaction.

Healthcare providers are not required by Federal law to obtain the signature of the patient or their representative acknowledging receipt of the VIS. The VISs are not designed as informed consent documents. But while the federal government does not require informed consent for vaccinations, some states or organizations may require a signature. You should consult your agency or state immunization program to determine if there are any specific informed consent requirements.

Documentation that the VIS was given is required. Healthcare providers must note in each patient's permanent medical record or in a permanent office log or

file, the date printed on the VIS and the date the VIS is given to the vaccine recipient, or their legal representative. Every VIS is dated. The date is always located in the corner of the second page of the document, and sometimes on the first page as well. This is the date that must be recorded in the patient's chart. VISs change periodically. Paying attention to this date also helps to ensure that your office always has the most current version of each VIS. Speaking of most current versions, this graphic lists Vaccine Information Statements that are new or revised since our last Immunization Update broadcast in August 2004. There are new statements for yellow fever and Japanese encephalitis vaccines, for those of you who vaccinate travelers.

VISs for influenza vaccine – both TIV and LAIV – have been revised for the 2005-2006 influenza season. A revised meningococcal VIS is available now that includes both the polysaccharide and conjugate vaccines. We have received many requests for a VIS for the new Tdap vaccines. We have not yet developed a Tdap statement. We hope to have an interim document in the next 1 to 2 months. In the mean time you should use the existing Td VIS, and supply the person with a copy of the package insert if they request it. As a general rule, it is not necessary to throw out your old statements, except influenza, unless a major change has been made. Just replace your supply with the new version when you run out of the older version.

All English language Vaccine Information Statements are available from the National Immunization Program and state immunization programs. VISs are available in more than 25 languages on the Immunization Action Coalition website. You will also find audio versions of the VISs on the NIP website. We will have a link to all the Vaccine Information Statements on our broadcast resources website.

Global Polio Eradication

For our last vaccine brief, we would like to update you on the status of global polio eradication. The Global Polio Eradication Initiative was launched by the World Health Assembly in 1988. At that time 125 countries were considered endemic for wild poliovirus. The World Health Organization, CDC, Rotary International, and UNICEF are the principal partners. National governments, private foundations, nongovernmental organizations, corporations, and volunteers are all collaborating to achieve eradication. The last known case of paralytic disease caused by wild polio virus in the United States occurred in 1979. The Pan American Health Organization devised an aggressive – and successful – OPV mass vaccination program in 1985. The last case of wild virus polio in the entire western hemisphere occurred in Peru in 1991.

Due largely to the success of the polio elimination program in the Americas, the World Health Organization established a polio eradication program in 1988.

This map shows in red the countries with poliovirus transmission in 1988, the year the global eradication program began. That year, more than 350 thousand cases occurred in at least 125 countries, including much of central and south America, parts of Europe, all of Africa and most of Asia.

In 2004 a total of only 1,255 cases of polio were reported from 18 countries, shown on this map in red. Polio is considered to be endemic in only six of these countries – Nigeria, Niger, Egypt, Afghanistan, Pakistan, and India. Transmission of polio has been re-established in several neighboring countries. The remaining six countries reported imported cases. More cases were reported in 2004 than in 2003 because of a large outbreak in Nigeria. The outbreak in Nigeria was a result of cessation of vaccination activities in one northern state of the country. This outbreak led to re-establishment of transmission in neighboring countries, and importation into 6 additional countries. In 2004 Nigeria accounted for more than 700 of the approximately 1000 reported cases worldwide. Fortunately, vaccination activities have begun in northern Nigeria again and the outbreak should soon be controlled.

Several challenges to global eradication remain. Among them: rapidly stopping polio transmission in the remaining endemic areas. Poliovirus can be exported from these endemic areas into polio-free areas such as Angola and Indonesia; maintaining high quality disease surveillance so that all cases of polio can be identified quickly; and ensuring political and financial support until certification of global eradication is achieved.

You may be able to help meet at least one of these challenges. CDC continues to recruit healthcare professionals for short-term field assignments to polio endemic countries. This program is called Stop Transmission of Polio, or STOP. Here is Virginia Swezy, the STOP Activity Team Leader, to tell you about it.

The global program for polio eradication began following a world health assembly resolution in 1988, when ministries of health of all countries resolved to eliminate this terrible disease. In partnership with ministries of health, this effort is spearheaded by the world health organization, UNICEF, Rotary International and the Centers for Disease Control and Prevention. Over the years, CDC has provided technical expertise to the partnership of WHO, UNICEF and to individual countries, especially in epidemiology, surveillance and laboratory science. The Stop Transmission of Polio, or STOP, program is an effort to provide human resources for the polio eradication effort. The global polio eradication initiative is now in its final phase. But the challenges that remain are the most difficult ones.

In 1998, CDC initiated the STOP team program. Its objective is to accelerate the progress of the polio eradication program. The STOP program deploys teams of public health professionals to provide additional field support where it is needed most. Teams collaborate with national counterparts from the ministry of health, who and UNICEF in support of the strategies. In 1999, the first group of 25 STOP team members were assigned to 5 countries – Bangladesh, Yemen, Burkina Faso, Nepal and Nigeria. Since that time, 19 STOP teams, comprised of nearly 650 health professionals, have been assigned to 57 different countries. In 2002, based on the expressed needs of a number of countries, the STOP program expanded beyond polio to include data management support at the national level, as well as measles mortality reduction activities in a few countries. In 2004, STOP expanded even further to include strengthening childhood

immunization programs. The teams that are sent out now typically support all of these programs.

The duties of the team members vary depending on the needs of the country of assignment and the skills of the STOP team member. Once in country, team members are typically assigned to different districts and must work independently. Over the course of the 3-month assignment, team members may conduct and evaluate active disease surveillance, assist with case investigations and follow-up as well as conduct measles outbreak investigations, help with planning, implementing and evaluating mass immunization campaigns such as National Immunization Days, and develop and strengthen data management systems for the country's immunization program.

Each day is different for team members. They may work with local religious leaders to overcome rumors about the safety of the vaccines, train traditional healers about disease surveillance, travel to a remote island to investigate a suspected polio case, or give a presentation to health officials on immunization campaign coverage.

So who makes up the STOP teams? And what qualifications are we looking for? STOP team members come from diverse backgrounds. They are qualified public health professionals from all over the world. The common link among all STOP team members is an appreciation and understanding of public health, surveillance and epidemiology. This assignment is demanding. Team members are assigned to the poorest countries in the world. Once there, team members will travel to the highest risk areas to conduct surveillance, investigate cases and participate in vaccination activities. Those who accept to go on this assignment have strong professional expertise as well as the ability to work comfortably outside of their own culture. Critical to the success of this assignment is the ability to work well with people of a different culture and to work in difficult climates. Team members are expected to live at the district level, in areas which may lack medical facilities, familiar food or comfortable accommodations.

A STOP team assignment isn't for everyone. But it can be a very rewarding experience. If you are interested and would like additional information, please contact us. This could be your opportunity to participate in one of the greatest achievements of public health history, the eradication of polio virus from the Earth.